

REMARKS

I. Status of the Claims

Claims 1, 2 and 4-15 are pending in the application, and claims 10-14 stand withdrawn. Thus, claims 1, 2, 4-9 and 15 are under consideration and stand rejected under 35 U.S.C. §103 as obvious. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejection Under 35 U.S.C. §103

Claims 1, 2, 4-9 and 15 stand rejected as obvious over either Wreschner A (2005) in view of Hoogenboom *et al.*, Capon *et al.* and Wreschner B (1996). Applicants traverse.

According to the examiner, Wreschner A and Hoogenboom teach sequences identical to the instant SEQ ID NOS: 19 and 23, but admittedly do not teach chimeras between MUC1 and Fc. These deficiencies are said to be corrected by Capon and Wreschner B, which allegedly teach Fc fusions and various forms of MUC1, respectively. From this, the examiner picks and chooses the relevant teachings from the art to arrive at applicants' invention. As explained below, the rejection is improper.

Assuming that the examiner properly characterizes the art with respect to what elements of the presently claimed invention are disclosed, the question remains: why would one choose to combine the Fc fusion technology of Capon with the MUC1 teachings of Wreschner A/B and Hoogenboom? The examiner's take on this issue is that the skilled artisan would make the combination simply "to prolong the *in vivo* plasma half-life of soluble MUC1 extracellular domains for inhibiting the growth of breast cancer in patients." Yet interestingly, none of the three references dealing with MUC1, *all of which were published after Capon*, felt any need to

cite to Capon, much less incorporate its teachings, to achieve the goal of improved plasma half-life. Thus, it seems that the examiner is in fact substituting her subjective views to what would or would not be obvious to combine, while ignoring fairly clear implications to the contrary from the very people whose art is being cited.

As further evidence that the examiner's thoughts on motivation to combine are wrong, applicants submit the following. Reading Capon, there is no discussion to indicate that adding an Fc molecule to a ligand would have any practical benefit *for producing antibodies*. In fact, it is well accepted that producing antibodies can be achieved, in most cases, simply by repeated administration of significant quantities of antigen. Clearly, as the examiner has shown, MUC1-EC was a well known antigen and could have been produced and administered for the purpose of antibody production without the need to engage in the complicated engineering called for by Capon.

Turning to the MUC1 references, Wreschner A discusses for the most part the use of *ligands* to MUC1-EC. This is reflected throughout the specification, and where it does discuss administering MUC1-EC, *it is solely for the purpose of producing antibodies*. As such, the combination of Capon with Wreschner A simply does not make sense.

Wreschner B has a similar, though more subtle inconsistency with Capon. While there is discussion of administering the compositions of Wreschner B to a subject for therapy, the only *claim* directed to that subject matter, claim 14, carefully excludes subject matter where the MUC1 receptor lacks tandem repeats. This distinguishing language is also found at page 12 of the application in the second full paragraph. Thus, while tandem repeat deletions might have been suitable as pharmaceutical agents for the production of antibodies, as in Wreschner A, they were clearly *not* intended for use as therapeutics *per se*. Again, with the only possible suggested

in vivo use of such compositions as antibody generating agents, this would *not* precipitate their combination with the complicated Capon technology by the skilled artisan.

Moreover, it is a well known patent law tenet that the properties of a compound must be considered in determining the patentability of that compound. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). In that regard, applicants are providing the declaration of one of the inventors, Dr. Surender Kharbanda, that contains data showing that an Fc-MUC1-ED fusion has activity against cancer cells both *in vitro* and *in vivo*. While Wreschner (A) suggests administering a MUC1-EC peptide to subjects for the treatment of cancer, the clear implication of that reference is that the peptide will generate protective antibodies. Nothing in Wreschner (A), or any other cited reference for that matter, suggests that the peptide could *directly* inhibit cancer cells.

III. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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